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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,466	07/09/1999	MARK T SPITLER	CHEMM-101XX	8173

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EXAMINER	
CROSS, LATOYA I	
ART UNIT	PAPER NUMBER
1743	19

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-19

Office Action Summary	Application No.	Applicant(s)	
	09/350,466	SPITLER ET AL.	
	Examiner	Art Unit	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12-18-03* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-23,25-29,31-34 and 37-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-23,25-29,31-34 and 37-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 30, 2002 has been entered.

Withdrawal of Rejections from Previous Office Action

- The rejection of claims 21, 23, 26-33, 34, 37, 38 and 40-42 under 35 USC 102(b) over Clement and the rejection of claims 22, 24, 25, 34, and 39 under 35 USC 103 over Clement in view of Burleigh are withdrawn in view of Applicants' argument that the analysis element of Clement requires the analyte to react with the reagent component to form a visible color change, whereas in the instant invention, the already present color is desorbed to the top layer of the element to denote the presence of the analyte.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 21-23, 25-29, 31-34, 37, 38 and 40-45 rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,822,280 to Haas.

Haas teaches a indicator element having a front layer (12) and a back layer (14). The front layer contains a transparent display layer (30), an opaque viewing layer (31) and an adhesive (36). One side of the opaque viewing layer is viewable through the transparent layer. The other side of the opaque viewing layer contains a dye or ink material (col. 9, lines 11-18). The back layer includes an activation agent (20) and a support (40). The activation agent may also be absorbed in the opaque viewing layer. The activation agent contacts the dye or changes the properties of the viewing layer to enable the dye to migrate there through and be seen through the transparent layer. See col. 9, lines 19-32 and col. 9, line 66 – col. 10, line 12. The opaque viewing layer is described as being able to assist in preventing dispersion of the dye and in producing a sharp color change. This layer is equivalent to Applicants' claimed second region. As the activation agent, Haas teach using an ester plasticizer, such as diisodecyl phthalate (col. 11, lines 34-35). In use, the dye is substantially non-migrating through the opaque viewing layer. After expiration of a predetermined time, the plasticizer concentration reaches a critical point where the dye is able to migrate into the viewing layer. The appearance of color in the viewing area signals the end of predetermined time interval. At col. 12, lines 20-37, Haas teach that the indicator element may be used as a time temperature food spoilage

indicator wherein time and temperature levels are being monitored to determined whether food spoilage may have occurred.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(e) in view of the teachings of Haas.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 22, 24, 25, 34 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haas in view of US Patent 4,421,719 to Burleigh (hereinafter Burleigh '719).

The disclosure of Haas is given above.

Haas does not disclose the use of solids such as those recited in claims 22 and 39, having radiant energy detectable materials absorbed thereon. Haas also does not disclose a single layer analytical element.

Haas teaches colorimetric indicators comprising an indicator substance coated on a backing. The indicator, which may be a dye, dye precursor, or bleachable dye, reacts with a selected substance and changes color to denote the presence of the selected substance. The indicator substance is absorbed onto an absorbent carrier such as alumina, silica or carbon and is affixed to a suitable substrate (backing) via a clay mineral binder.

It would have been obvious to one of ordinary skill in the art to use such carrier coated indicators, as disclosed by Burleigh '719, since the porosity of carriers like alumina, silica, and carbon allows the indicator substance as well as toxic substances to be absorbed thereon. As taught by Burleigh '719, at col. 3, lines 30-33, high surface area materials such as these serve as a medium for toxic substance absorbency, thereby allowing a more accurate detection of such.

With respect to claims 24 and 25, it would have been obvious to one of ordinary skill in the art, at the time of Applicants' invention, to construct the analytical device in any manner most convenient and efficient for its use. Single layer analytical elements (mostly test strips having non-discrete layers) are conventionally used in the art where selective migration of materials must be conducted. It does not appear that the use of a single layer provide any advantage over multiple layered elements.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Haas in view Burleigh '719.

Response to Arguments

8. Applicant's arguments with respect to the instant claim have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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February 24, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700